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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,911	07/31/2003	Royce S. Fishman	AGALIN 3.0-003 II	9615
530	7590	06/12/2006	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			MITCHELL, TEENA KAY	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/631,911	Applicant(s) FISHMAN ET AL.	
	Examiner Teena Mitchell	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)     | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

**The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

**(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.**

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.**

**Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickie (6,807,965) in view of Ujhelyi et.al. (6,728,574).**

With respect to claim 1, Hickie in an apparatus for relief from pain and anxiety associated with medical procedures discloses a care system (10) a drug delivery system (40) which delivers one or more gaseous sedative, analgesic or amnestic drugs in combination with O<sub>2</sub> gas, an electronic controller (14) and remote control device (45). Hickie does not disclose that the medical procedure is used for easing a patient's pain from atrial or ventricular defibrillation. Ujhelyi in a pain-controlling device teaches that is known to provide an inhalable gas to a patient from atrial or ventricular defibrillation (Col. 3, lines 64-67 and Col. 4, lines 1-16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the medical gas of Hickie to a patient receiving atrial defibrillation as such procedures as taught by Ujhelyi are known to cause pain and anxiety. Based on the capabilities of the controller and the

remote control device of Hickle it would be obvious that the remote information relating to atrial defibrillation a third party (i.e., a doctor) can consider the information and assist said patient in inhaling said effective amount of medical gas. Based on the knowledge of a doctor the amount of gas given a user based on individual users the analgesia, sedative or amnestic ([0060]) the gas would be able to produce the effects immediately prior to, during and immediately after activating said atrial defibrillation device. With respect to the newly added limitation of, "...for a period of up to six minutes..." based on applicant's disclosure [0169] and [0170] the length of the pre-determined period of time between the beginning of gas administration and the FA-ICD shock depends on many factors. Thus the length of the pre-determined time period may depend on the nature and dose of the analgesic gas, among other factors.....The pre-determined time period may also vary from patient to patient, depending on factors such as age, weight and pain tolerance..." Therefore the newly added limitation based on applicant's own disclosure would be obvious to one of ordinary skill in the art to include the newly claimed limitation of up to six minutes, based upon many factors including the nature of the dose and the individual user, as noted in [0169] and [0170] paragraphs.

With respect to claim 2, Hickle discloses a gas that provides a sedative, analgesic, or amnestic drug. It would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to have the medical gas one of the claimed gases as one of ordinary skill in the art would look to select a known gas, which would provide the analgesia or amnesia effects. Therefore, the use

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of the claimed gases is deemed to be a design consideration, which fails to patentably distinguish over the prior art of Hickie.

With respect to claims 3, 4, 8, 18, 19, 27, and 31 note rejection of claim 2 above.

With respect to claim 5, note rejection of claim 1 above. It would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to have the atrial device be an atrial fibrillation implantable cardioverter defibrillator as such devices are well known in the art and applicant has not disclosed that the use of an atrial fibrillation implantable cardioverter defibrillator provides an advantage or solves any stated problem.

With respect to claims 6, 7, 9, 14, 15, 17, 20, -26, 29, and 30 note rejection of claim 1 above.

With respect to claim 9, note rejection of claim 1 above.

With respect to claims 10-12, and 16, note rejection of claim 2 above.

With respect to claim 13, note rejection of claim 5 above.

With respect to claim 23, note rejection of claim 1 above.

### ***Response to Arguments***

Applicant's arguments filed 3/23/06 have been fully considered but they are not persuasive. Based on applicant's own disclosure paragraphs [0169] and [0170] the limitations of the specific time is based upon many factors which one of ordinary skill in the art would know and therefore be able to arrive at the specific claimed time ranges, as the nature of the gas and the individual user all play a part on how fast and to what

degree the gas will work and give the respectively effect needed prior to the atrial defibrillation.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Teena Mitchell  
Primary Examiner  
Art Unit 3743  
June 4, 2006

  
TKM